



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

20

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,243	12/27/2001	Karen L. Fearon	377882001800	8533
25226	7590	10/25/2006		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER DUFFY, PATRICIA ANN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/033,243

Applicant(s)

FEARON ET AL.

Examiner

Patricia A. Duffy

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10-11-06 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 10-11-06. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-4, 9-21, 24, 26, 47 and 48.
Claim(s) withdrawn from consideration: 5-8 and 27-46.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Pat A. Duffy
Patricia A. Duffy
Primary Examiner
Art Unit: 1645

Continuation of 5. Applicant's reply has overcome the following rejection(s): rejection of claims 9-21 and 48 at bottom of page 2 of the final rejection.

Continuation of 11. does NOT place the application in condition for allowance because:

With respect to the enablement rejection, applicants argue that the specification teaches how to assay ISS activities. This is not persuasive because the only activity that the recited ISS have is the increase of IFN gamma or alpha. None of the other recited activities of immune stimulation IL-4, IL-5 have been demonstrated to be associated with recited sequences. The term "immunostimulatory" encompasses any means or measures of immunostimulation and aside from the recited interferons, applicants are not enabled for the full scope of responses of all stimulatory or immune cytokines or measureable parameters. Applicants have not associated the full scope of the asserted measureable parameters with any structure. Applicants definition includes any measureable response. Applicants have not enabled any measurable response and have not provided nucleic acid structures corresponding to such. Applicants have not provide structures that provide for a Th1 immune response or the increase in the associated cytokines. Applicants have not provided for any structures that provide for induction of tolerance or suppression of an immune response. As such, the generic teachings are not enabled for their scope as previously set forth. Applicants argue that the examiner has not provided evidence that the immunostimulatory response is unpredictable. References are not required to establish unpredictability. More is required when the application is devoid of teachings of the scope of the invention, especially as the art is silent and particularity discloses that more than half of the "immune responses" that fall within the scope of the definition are not associated with the claimed CpG sequences and the art also recognizes that not all CpG containing sequences stimulate IFN gamma or alpha. References and rationale was cited. The fact that the full scope of the claims is not enabled is clearly recognized in the background of the disclosure that indicates that CpG sequences induce Th2 as opposed to Th1 cytokines (IL-4 or IL-5). Therefore, applicants own specification clearly states that the full scope is not enabled and the working examples does not provide evidence that these other types of immune response are also stimulated by the claimed CpG sequences. Applicants working examples are not commensurate with the claimed invention for the plethora of reasons already made of record. The other working examples fall to oligodeoxynucleotides that do not fall within the instant claims. Applicants should point to specific oligonucleotides, including ribose-based oligonucleotides in the specification that show activation or expansion of lymphocyte populations, such as NK, CD4+, CD8+, T lymphocytes, B, lymphocytes, IL-4 and IL-5 cytokines etc to enable the full scope of the invention. Applicants have not taught a number of ISS ribose or deoxyribose based nucleotides that provide for immunostimulatory activity for the full scope of the invention. Applicants arguments are not persuasive. Applicants reiterate the generic teachings of the specification and that any of the substitutions will work in view of the consensus sequences. Applicants arguments are not persuasive in view of the scope of the invention and the lack of evidence to support Applicants' argument that each specie in the genus works for the full scope of the invention.

Applicants arguments with respect to the art rejection is not persuasive because the nucleic acid at hand is 480 base pairs and the art contemplates fragments of the invention that anticipate the instantly claimed invention. To anticipate the prior art must nearly teach the composition. The prior art does not have to teach the same use or contemplate the same use. As such, Applicants arguments are not persuasive.